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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,290	09/18/2003	Madaline Chirica	DX01074B1	8667
28008	7590	03/23/2007	EXAMINER	
DNAX RESEARCH INC. LEGAL DEPARTMENT 901 CALIFORNIA AVENUE PALO ALTO, CA 94304			SEHARASEYON, JEGATHEESAN	
			ART UNIT	PAPER NUMBER
			1647	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,290	CHIRICA ET AL.	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 24 and 26-29 is/are rejected.
- 7) Claim(s) 25 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/18/2003 and 7/28/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input checked="" type="checkbox"/> Other: <u>Appendix A1-2</u> . |

DETAILED ACTION

1. This Office Action is in response to Applicant's election without traverse of Group I drawn to claims 24-29 filed 12/22/2006 is acknowledged. Claims 30-38 are cancelled. Therefore, Claims 24-29 are pending and are examined.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. Applicant is required to update the priority information by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

4. The IDS submitted 9/18/2003 and 7/28/2005 have been considered.

Claim Objections

5. Claim 25 is objected to because of the following informalities: Claim 25 is objected to because it is dependent on rejected claim 24. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1647

6a. Claim 24 is rejected as being vague and indefinite in the recitation of the term "antigenic polypeptide". The specification provides no support for "antigenic polypeptide". It is unclear if the antigenic polypeptide needs to be of a certain amino acids length (e.g. 6 contiguous amino acids) or they are capable of being antigenic. The specification discloses several polypeptide sizes (see pages 3-4). Claims 26-29 are rejected insofar as they depend claim 24.

6b. Claims 26, 27 and 29 are rejected as being vague and indefinite in the recitation of the term "IL12R β 1 polypeptide or IL-B30/p40 polypeptide". Abbreviations and acronyms should be spelled out at their first use in the claims for clarity. The protein of interest is described by an arbitrary abbreviation. It is unclear from which species the said protein was isolated. Applicant should particularly point out and distinctly claim the IL12R β 1 or IL-B30/p40 by claiming structural characteristics associated with the protein (e.g. amino acid sequence, molecular weight, etc.). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. Claims 24 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification while enabling for polypeptide of SEQ ID NO: 2 or polypeptide

of SEQ IDNO: 2 from amino acid 1 to amino acid 101 or polypeptide of SEQ IDNO: 2 from amino acid 102 to amino acid 195 or polypeptide of SEQ IDNO: 2 from amino acid 196 to amino acid 297 or polypeptide of SEQ IDNO: 2 from amino acid 1 to amino acid 328 or polypeptide of SEQ IDNO: 2 from amino acid 1 to amino acid 606, does not reasonably provide enablement for all possible polypeptide fragments contemplated by the Applicant. The claims recite the phrase “an antigenic polypeptide” and thus, are broadly interpreted by the Examiner as reading upon: (i) fragments of SEQ ID NOs: 2, including sequences only 6 amino acids in length (see specification page 3). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention as claimed.

The instant claims reads on polypeptide fragments of SEQ ID NO: 2. The claims recite the phrase “an antigenic polypeptide” and thus, are broadly interpreted by the Examiner as reading upon: (i) fragments of SEQ ID NOs: 2, including sequences only 6 amino acids (see specification page 3). The claims also read on fragments of SEQ ID NO: 2 and IL-12 β 1 binding IL-B30/p40.

However, other than the polypeptide of SEQ ID NO: 2, the specific fragments of SEQ ID NO: 2 disclosed in the instant claims, the specification as filed fails to disclose any other sequence contemplated in the instant claim such as “an antigenic polypeptide”. In addition, while the specification teaches that p40/IL-B30 ligand binds with receptor subunits DCRS5 (SEQ ID NO: 2) and IL-12 β 1 (see page 7), it does not teach fragments of SEQ ID NO: 2 binding p40/IL-B30. The specification does not teach

functional or structural characteristics of the polypeptide fragments encompassed by the claims.

Despite knowledge in the art for producing fragments of polypeptides, the specification fails to provide any guidance regarding the polypeptide fragments contemplated in the methods that retain the function. Furthermore, detailed information regarding the structural and functional requirements of the disclosed protein is lacking. Although it is accepted that the amino acid sequence of a polypeptide determines its structural and functional properties, predicting a protein's structure and function from mere sequence data remains an elusive task. The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine,

without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized procedures for producing and screening for active variants, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. Therefore, predicting which polypeptide, if any, would retain the functions of the protein is well outside the realm of routine experimentation. Further, since no function has been attributed to the claimed protein, the skilled artisan would not know what function to test for. Thus, an undue amount of experimentation would be required to generate the changes/modifications contemplated and yet retain the function of the proteins claimed.

Applicant has not taught how one of skill in the art would use the full scope of amino acid sequences encompassed by the invention of claims 24 and 26-29. The specification as filed does not sufficiently teach one of skill in the art how to make and/or use the full scope of the claimed sequences. The amount of experimentation required to make and/or use the full scope of the claimed sequences would require trial and error experimentation to determine the functional sequences.

Given the breadth of claims 24 and 26-29 in light of the unpredictability of the art as determined by the lack of working examples and shown by the prior art of record, the level of skill of the artisan, and the lack of guidance provided in the instant specification, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claims 26-29 are rejected insofar as they are dependent on rejected claim 24.

7b. Claims 24 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses the polypeptide sequence of SEQ ID NO: 2, the specific fragments of the polypeptide sequence of SEQ ID NO: 2 disclosed in the claims. This meets the written description provisions of 35 USC 112, first paragraph. However, the specification does not disclose all possible amino acid fragments of SEQ ID NO: 2 contemplated by the Applicant. The claims recite the phrase “an antigenic polypeptide” and thus, are broadly interpreted by the Examiner as reading upon: (i) fragments of SEQ ID NOs: 2, including sequences only 6 amino acids (see specification page 3).

The claims as written, however, encompass variant sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112,

first paragraph because the written description is not commensurate in scope with the recitation of claims 24 and 26-29. The specification does not provide written description to support the genus encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

With the exception of the polypeptide of SEQ ID NO: 2, the specific fragments of polypeptide of SEQ ID NO: 2 disclosed in the instant claims, the specification as filed fails to disclose any other sequence contemplated in the instant claim such as “an antigenic polypeptide”. Thus, the skilled artisan cannot envision all the detailed chemical structure of the claimed polypeptide sequences regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only the polypeptide of SEQ ID NO: 2, the specific fragments of the SEQ ID NO: 2 disclosed in the instant claims, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of various

polypeptide sequences set forth in claims 24 and 26-29. Claims 26-29 are rejected insofar as they are dependent on rejected claim 24.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8a. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (1992).

Claims are drawn to isolated polypeptide. The claims recite the phrases "an antigenic polypeptide" and thus, are broadly interpreted by the Examiner as reading upon: (i) fragments of SEQ ID NOs: 2, including sequences 6 amino acids in length (see specification page 3).

Wang et al. (1992). discloses an antigenic polypeptide of SEQ ID NO: 2 (see Appendix A1-2). The examiner is broadly interpreting "an antigenic polypeptide" to include fragments of the polypeptide that are at least 6 amino acids long and thus, the

reference anticipates the antigenic polypeptide of SEQ ID NO: 2. Therefore, claim 24 is rejected as being anticipated by Wang et al. (1992). However, this rejection maybe obviated by Applicant rewriting the claim as follows "An isolated or recombinant polypeptide of SEQ ID NO: 2".

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b)..

9a. Claim 29 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of U.S. Patent No. 6, 756, 481. Although the conflicting claims are not identical, they are not patentably distinct from each other because the kit disclosed in the instant invention and that of the allowed patent contain an antibody that binds to SEQ ID NO:2.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chirica et al. (U. S. Patent No. 6, 756, 481) disclose antibodies binding to SEQ ID NO: 2 of the instant invention. The instant Application is a DIV of the previously allowed patent.

11. Claims 25 will be allowable if written independent of rejected claim 24. Claims 24 and 26-29 are not allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gaganesh Ibarajey

Patent Examiner

JS

Art Unit 1647,
October 25, 2006

A;Residues: 1-917 <RE2>
A;Cross-references: UNIPARC:UPI00002845A; EMBL:X62646; NID:g840816; PIDN:CAA44515.1;
C;Genetics:
A;Gene: gp130
C;Keywords: glycoprotein
F;134-314/Domain: cytokine receptor homology <CRS>

RESULT 2

A44257
interleukin-6 signal transducing molecule gp130 - rat
C;Species: Rattus norvegicus (Norway rat)
C;Date: 30-Apr-1993 #sequence_revision 18-Nov-1994 #text_change 09-Jul-2004
C;Accession: A44257
R;Wang, Y.; Nesbitt, J.E.; Fuentes, N.L.; Fuller, G.M.
Genomics 14, 666-672, 1992
A;Title: Molecular cloning and characterization of the rat liver IL-6 signal transduci
A;Reference number: A44257; MUID:93052397; PMID:1427893
A;Accession: A44257
A;Status: preliminary; not compared with conceptual translation
A;Molecule type: mRNA
A;Residues: 1-918 <WAN>
A;Cross-references: UNIPROT:P40190; UNIPARC:UPI000012D4D8
A;Experimental source: liver
A;Note: sequence extracted from NCBI backbone (NCBIP:118488)
C;Keywords: transmembrane protein
F;134-315/Domain: cytokine receptor homology <CRS>

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Query Match           6.8%;  Score 225.5;  DB 2;  Length 918;
Best Local Similarity  26.2%;  Pred. No. 1.4e-06;
Matches   86;  Conservative  60;  Mismatches  121;  Indels   61;  Gaps    18;
Qy          32 GHIWVEPATIFKGMNISIYCQAAIKNCQPRKLH----FYKNGI---KERFQITRINKT 83

```

Appendix A 2

Applicant Copy

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Db	86	ASSVTFTDVVFQNVQLTCNILSFGQIEQN-VYGITILSGYPPDIPTNLSCIVNE-GKNML	143
Qy	144	CTWNAXKLTYIDTKYVVHVKSLETEE---EQQYLTS-----YINISTDSLQGGK	190
Db	144	CQLDPGRETYLETNYTLK-SEWATEKFPCRTKHGTSSCMMGYTPYFVNIE-----	194
Qy	191	KYLVWVQAANALGMEESKQLQIHLDIVIPSA---AVISRAETINATVPKTIIYW--DSQ	245
Db	195	--VVVEAENALGNVSSEPINFDPVDKVKPSPPHNLSTNSEELESSILK--LAWVNSGL	248
Qy	246	TTIEKVSCEMRYKATTNQTWNVKEFD----TNFTYVQQSEFYLEPNIKYVFQVR-CQE	298
Db	249	DSILRLKSDIQYRTKDASTWIQVPLEDTVSPRTSFT-VQD---LKPFTEYVFRIRSIKE	303
Qy	299	TGKRYWQPWSSPFHKTPETVPQVTSKA	326
Db	304	NGKGYWSDWSEEASGTTYEDRP---SKA	328

RESULT 3

A36337
membrane glycoprotein gp130 precursor - human
C;Species: Homo sapiens (man)
C;Date: 12-Apr-1991 #sequence_revision 12-Apr-1991 #text_change 09-Jul-2004
C;Accession: A36337
R;Hibi, M.; Murakami, M.; Saito, M.; Hirano, T.; Taga, T.; Kishimoto, T.
Cell 63, 1149-1157, 1990
A;Title: Molecular cloning and expression of an IL-6 signal transducer, gp130.
A;Reference number: A36337; MUID:91084844; PMID:2261637
A;Accession: A36337
A;Status: preliminary
A;Molecule type: mRNA
A;Residues: 1-918 <HIB>
A;Cross-references: UNIPROT:P40189; UNIPARC:UPI0000046B12; GB:M57230; NID:g186353; PID:
C;Genetics:
A;Gene: GDB:IL6ST; GP130
A;Cross-references: GDB:126725; OMIM:600694
A;Map position: 5q11-5q11
C;Keywords: glycoprotein; membrane protein
F;134-316/Domain: cytokine receptor homology <CRS>

Query Match 6.3%; Score 209; DB 2; Length 918;
Best Local Similarity 19.5%; Pred. No. 1.6e-05;
Matches 173; Conservative 116; Mismatches 278; Indels 318; Gaps 44;

Qy	4 VTIQWDAIALYILFSWCHGGITNINCSGHIWEPATIFKMGMNISIYCQAAIKNCQPRK	63
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Db	2 LTLQTWVQALFIFLTTESTGELLDPC-GYISPE-SPVQLHSNFTAVC--VLKEKCMDY	57
Qy	64 LHFYKNGI-----KERFQITRINKTARLWYKNFLEPHASMYCTAECPKHFQETL	113
	:: : : : : : : : :: :	
Db	58 FHVNANYIVWKTNHFTIPKEQYTI--INRTASSVTFTDIASLNIQLTCNILTGFQLEQN-	114
Qy	114 ICGKDISSGYPPDIPDEVTCVIYEYSGNMCTWNAXKLTYIDTKYVVH-----	161
	: : :: :: : : :: : :	
Db	115 VYGITIISGLPPEKPKNLSCIVNE-GKKMRCEWDGGRETHLETNFTLKSEWATHKFADCK	173